

October 5, 2015

State of Michigan Legislature  
Lansing, MI 48909-7536

RE: Biosimilar Substitution (in reference to, but not limited to, HB 4812 and HB 4437)

Dear Legislator,

Diplomat Pharmacy, Inc. ("Diplomat") appreciates the proposed regulations to define biosimilars and interchangeability in response to the federal law changes and federal agency guidance documents. Diplomat supports the proposed approach to incorporate the definition of biosimilars (§010.06) and interchangeability (§010.40) into Michigan's Board of Pharmacy Rules and also supports proposed §130.04: Drug Product Selection: Biosimilars to allow for automatic substitution of interchangeable biosimilars.

Diplomat, headquartered in Flint, Michigan, is the nation's largest independent specialty pharmacy. As a specialty pharmacy, biologics comprise a great deal of the prescriptions we provide to our patients. We are currently caring for nearly 20,000 patients who receive biologic therapy. Availability of biosimilar products has the potential of reducing healthcare costs and improving access for these patients; however, should physician notification be required for biosimilars *already deemed interchangeable*, we feel that patient access will be greatly impaired and Michigan business will become disadvantaged.

It is Diplomat's position that a requirement to notify the physician is unnecessary and will delay provision of medications in patient populations where barriers already proliferate. The requirement is unnecessary because biosimilars deemed interchangeable by the FDA must be expected to produce the same clinical result as the reference product, and safety and efficacy shall not vary whether a patient alternates between a biosimilar and its reference product or remains on the reference product. The requirement is also unnecessary as prescribers of biologics maintain a responsibility to be aware of available medications for the conditions they treat; should a prescriber prefer a patient receive the reference product or specific biosimilar, he or she can specify so on the prescription. Furthermore, working with the Michigan Association of Health Plans (MAHP), Diplomat supports the use of biosimilars and interchangeables to provide patient access to these newer high-quality drug therapies while also potentially reducing health care costs. If physician notification is required, current and future patients, both of Diplomat and other pharmacies, will face delays in therapy critical to their health.

In addition to patient access barriers, we have significant concerns for the impact of physician notification mandates on Michigan pharmacies and health-related spending in the state. A notification mandate will cause loss of potential savings to the state of Michigan by slowing the rate of biosimilar adoption. It will also create a competitive disadvantage to Michigan companies competing nationally for biosimilar business. This could result in the loss of both significant revenue to Michigan business as well as the associated tax income to the state.

Diplomat appreciates the opportunity to provide comments and supports regulations that promote consumer access to biosimilar agents. If you have questions regarding Diplomat's position, please contact Phil Hagerman, Diplomat Chairman and CEO and Michigan resident at (810) 768-9453 or

[email@diplomat.is](mailto:email@diplomat.is). Alternatively, you may contact Michigan Pharmacists Association CEO, Larry Wagenknecht, at (517) 377-0226 or [larry@michiganpharmacists.org](mailto:larry@michiganpharmacists.org).

Sincerely,



Phil Hagerman, RPh, Chief Executive Officer, Chairman of the Board of Directors



Jeff Rowe, RPh, Former Director of the Board of Directors



Jennifer Hagerman, PharmD, Associate Vice President, Education and Quality



Michael Crowe, PharmD, Clinical Technology Manager